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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,987	06/21/2001	Shigekazu Nagata	0020-4877P	5035

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EXAMINER
GUCKER, STEPHEN

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 06/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No	Applicant(s)
09/884,987	Nagata et al.
Examiner	**Group Art Unit**
Stephen Gucker	1647

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- [x] Responsive to communication(s) filed on 9/27/01.
- [ ] This action is **FINAL.**
- [ ] Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- [x] Claim(s) 1-11 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- [ ] Claim(s) _____ is/are allowed.
- [x] Claim(s) 1-11 is/are rejected.
- [ ] Claim(s) _____ is/are objected to.
- [ ] Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- [ ] See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- [ ] The proposed drawing correction, filed on _____ is [ ] approved [ ] disapproved.
- [ ] The drawing(s) filed on _____ is/are objected to by the Examiner.
- [ ] The specification is objected to by the Examiner.
- [ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- [x] Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).
  - [x] All [ ] Some* [ ] None of the CERTIFIED copies of the priority documents have been
  - [ ] received.
  - [x] received in Application No. (Series Code/Serial Number) 08/219,237.
  - [ ] received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

- [ ] Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- [ ] Interview Summary, PTO-413
- [x] Notice of Reference(s) Cited, PTO-892
- [ ] Notice of Informal Patent Application, PTO-152
- [ ] Notice of Draftsperson's Patent Drawing Review, PTO-948
- Other _____

Office Action Summary

Part III DETAILED ACTION

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3, 6-12, and 17 of U.S. Patent No. 6,270,998 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims 1-2 and 10 use open language in relation to SEQ ID NO:1 or SEQ ID NO:2 and instant claims 3-6 expand upon the scope of claim 1 by using further open language. The '998 patent claims the complete isolated DNA sequence of Fas antigen, including regions encoding the extracellular, transmembrane, and intracellular domains, plus expression vectors, host cells, and methods of producing the Fas antigen protein. The '998 patent does not claim the DNA sequence encoding only the intracellular domain *per se*. The instant claims recite open language comprising the encoding intracellular domain DNA sequence, but do not recite DNA sequences encoding the transmembrane or extracellular regions *per se*, but the open language recited would encompass the transmembrane and extracellular regions, i.e. the entire DNA

molecule encoding Fas antigen, for which a patent has already been granted. It would have been obvious to one of ordinary skill in the art at the time of the invention to make DNA comprising the intracellular region of Fas antigen because one making the complete Fas antigen would want to include the intracellular domain to retain functionality of the encoded protein. In addition, the artisan would want to use the encoding intracellular domain sequence of Fas antigen in order to make the intracellular domain without the other domain regions in order to seek out the intracellular binding partners that bestow upon the encoded protein its biological functionality, i.e. "programmed cell death" or apoptosis, particularly in relation to how the Fas antigen or its downstream partners could be activated in ways other than antibody binding to the extracellular domain of Fas antigen in order to kill cancer cells. Besides a terminal disclaimer, eliminating open language (i.e. "comprises" or "comprising") from the instant claims and rewriting the dependent claims into independent claims would obviate the grounds of this rejection.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 11 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using a polypeptide not inside a cell as an antigen, does not reasonably provide enablement for using a cell as an antigen. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with this claim. Claim 11 recites the intracellular

domain of Fas antigen. However, if one uses the cell expressing Fas antigen as an antigen, the antibodies so produced will be immunoreactive to the region of the antigen exposed to the immune system of the animal producing the antibodies, which is the extracellular region of Fas antigen, as demonstrated by one of the inventors' published work (see Yonehara et al., *J. Exp. Med., Vol. 169: 1748-56, 1989*). The specification does not provide an adequate written description or guidance as to how to make an antibody to the intracellular domain of Fas antigen by using a cell expressing Fas antigen as an antigen. There are no working examples of such antibody production taught in the instant specification. It would require undue experimentation by skilled artisans with no reasonable or predictable chance of success in order to make antibodies immunoreactive to an intracellular domain of a protein by exposing the immune system to cells expressing only the extracellular domain of the protein to the immune system.

5. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 10-11 are confusing because it recites "amino acid sequence of No. 175 to 319" when such sequences do not exist as SEQ ID NO:175 or SEQ ID NO:319. To avoid terminology confusion, it is suggested that the claims be rewritten as "amino acid residues 175-319 of SEQ ID NO:2". It is also strongly suggested to remove all "No." from the claims as this term often causes confusion with the printer's office as to the placement of terminal periods (yes, it's true), e.g. claim 2 should read "nucleotide sequence of bases 765-1199 of SEQ ID NO:1."

Additionally, Applicant should be aware that the word "comprises" used anywhere in the claim, regardless of the phrase "consisting of" in the same claim, makes the claim open and therefore such claims are obvious over US 6,270,998 B1, as set forth in ¶2 above. All of the claims of the instant Application must be considered open because otherwise, the dependent claims would not be proper dependent claims because they would not be further limiting in scope in relation to the independent claim from which they depend. An expression vector cannot be further limiting if the independent claim upon which it depends is excluded from "comprising" additional nucleotide bases that would make up the promoter regions, etc., of the expression vector. Or in other words, an independent claim that "consists" of a specified nucleotide sequence should not have a claim dependent on it that "comprises" an expression vector, as such a dependent claim would appear to be outside of and broaden the scope of the independent claim.

Claims 10-11 have improper dependencies. There is no cell of claim 6; it appears that cell of claim 7 was intended. There is no polypeptide of claim 7; it appears that polypeptide of claim 10 was intended.

Claim 11 is also vague and indefinite because it lacks explicit and discreet process steps for carrying out the process of making antibodies; only the phrase "utilizing as an antigen" is given which lacks clear metes and bounds for the process being claimed. The grounds for this part of the rejection could be obviated by amending the claim to explicitly recite individual process steps such as transfecting a host cell with DNA encoding Fas antigen and injecting said

host cell into an animal in order to raise antibodies to Fas antigen and then isolating said antibodies.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Yonehara et al. ("Yonehara"). Yonehara, one of the inventors of the instant Application, describes making anti-Fas antigen antibody by using human diploid fibroblast FS-7 cells as an immunogen (page 1747). The grounds of this rejection could be obviated by amending the claim to explicitly recite process steps such as transfecting a host cell with DNA encoding Fas antigen and injecting said host cell into an animal in order to raise antibodies to Fas antigen and then isolating said antibodies.

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (703) 308-6571. The examiner can normally be reached on Monday to Friday from 0930 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is currently (703) 308-4242, but Applicant should confirm this by phoning the Examiner before faxing.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SG

Stephen Gucker

June 18, 2003

Gary A. Kunz

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600